# SHIPPING DEVICE SUITABLE FOR BIOHAZARDOUS SPECIMENS

## BACKGROUND

Specimen envelopes are commonly used for patient-friendly specimen collection devices. These collection devices allow patients to obtain certain etiologic agents and/or biomedical materials in the privacy of the patient's home, and send the obtained materials for testing through the mail. For example, fecal specimens are delivered this way using Beckman Coulter Hemoccult® products. Shipping devices for specimens are well known in the art. For example, see U.S. Patent No. 5,150,971, which is incorporated herein by this reference. Other shipping devices are disclosed in U.S. Patent Nos. 5,918,983 and 5,921,396.

Recently the United States Postal Service has revised mailing standards relating to sending biohazardous materials in the mail. See, for example, Federal Register, Volume 68, No. 109, pages 33858-33873, June 6, 2003. One of the requirements for sending biohazardous substances is that a biohazard symbol be visible if the envelope is torn or inadvertently opened, exposing individuals to its contents.

Thus, there is a need for a shipping device which can safely be used for mailing biohazardous materials, and that satisfies the safety regulations of the U.S. Postal Service.

## SUMMARY

The present invention is directed to shipping devices that satisfies this need. In one version of the invention, such a device, which is typically in the form of an envelope, comprises a printed outer layer and a polymeric, water resistant inner layer having a printable surface facing the outer layer, wherein the two layers are joined together such as by lamination. There are printed indicia on the printable surface, with the result that the inner layer serves to protect the printed indicia from the contents of the mailing device.

Typically the laminate also includes a metallic, water-resistant, substantially non-light transmissive middle layer. Preferably, the printed indicia comprises biohazard indicia on a field of substantially solid printing.

The device can be formed by printing indicia on the printable surface of the inner layer, joining the outer and inner layers together such as by lamination, while including the optional middle layer at the same time.

In another version of the invention, there is a polymeric layer between the outer and middle layers to better effect lamination.

Another version of the invention is an envelope type device having a wall structure that comprises from outside to inside:

a. an outer layer;

b. a metallic, water-resistant, substantially non-light transmissive middle layer ;

c. a first polymeric layer having a printable surface facing away from the outer layer; and

d. a second polymeric layer protecting the printable surface, the second layer being substantially transparent,

wherein at least one of the first and second polymeric layers is substantially water proof, and wherein there is a printed biohazard warning on the printable surface of the first polymeric layer.

## DRAWINGS

These and other features, aspects, and advantages of the present invention will become better understood with reference to the following description, appended claims, and accompanying drawings where:

Fig. 1 is a perspective view of an embodiment of a shipping device according to the present invention, in an open position;

Fig. 2 is another perspective view of the device of Fig. 1 partially cut away to show internal printing where the device is in a sealed configuration;

Fig. 3 is a sectional view of a laminate suitable for forming the device of Fig. 1; and

Figs. 4 and 5 are sectional views of alternative laminates suitable for forming the device of Fig. 1.

## DESCRIPTION

With reference to Figs. 1 and 2, a specimen shipping device **100** having features of the present invention is depicted. Only some of the features shown in the drawings are required according to the present invention. Thus, the invention herein is not limited to the versions shown in the figures. The device **100** comprises a front panel **101a** and a back panel **101b** folded along a bottom crease **103** with opposed sides **105** and **107** securely sealed together by any suitable sealing method, such as by an adhesive, glue, or heat sealing. The first panel **101a** has mailing information printed thereon. The device **100** is preferably formed of a single sheet because sealing along the bottom crease **103** is not required; however, two separate sheets can be utilized, whereby a side corresponding to the crease **103** is sealed in a manner analogous to that used in the sealing of the sides **105** and **107**.

Referring now to the region of the device **100** opposite to the crease **103**, a test device insertion region **115** is defined by the termination of the front panel **101a** and the continuation of the back panel **101b**, whereby a pocket or pouch region is formed, generally being defined as the entire interior region between the sides **105** and **107**, the crease **103**, and the insertion region **115**. A flap **116** is defined by the extension of the back panel **101b** from the insertion region **115** to the termination of the back panel **101b**, and can include means for indicating the closing off and sealing of insertion region **115**. As an example of a means for indicating, a crease **120**, located about one-fourth of the distance of the flap **116** upwards from the insertion region **115**, defines the area of the flap **116** that is folded to secure an etiologic agent and/or biomedical material (not shown) which has been inserted into the pouch region of the mailing device **100**. Alternative means for indicating the closing off of the sealing insertion region **115** include, for example, instructions informing the user to fold the flap **116** at a point above the insertion region **115**, or hash-mark indicators located at about one-fourth to about one-half of the distance upwards from the insertion region **115**.

Fig. 2 shows the device **100** having the flap **116** folded along the crease **120** and in secure contact with an upper region of the side **101a**. By folding the flap **116** along the crease region **120**, the specimen device insertion region **115** (shown from a cut-away of flap **116**) is

advantageously located below the crease **120** and above a reference line **121** (shown in phantom) where the flap **116** and the front panel **101a** are approximately joined. This folding configuration negates the risk of leakage out from or into the region **115** in that the region **115** is covered and sealed. Such sealing is preferably effectuated by incorporation of an adhesive **130** on the flap **116** and a region **131** between the termination of the front panel **101a** and the crease region **120**. Thus, when the flap **116** is closed, the adhesive **130** secures the flap **116** to both region **131** and from the reference line **121** up to the insertion region **115**. The adhesive can be protected prior to use by removable protective tape (not shown). As an alternative to the use of an adhesive, sealing materials, such as, for example, an adhesive tape, can be applied to the flap **116** when it is in its closed position so that sealing thereof to the front panel **101a** is similarly effected.

The device **100** can optionally include tabs extending outwardly from flap **116** in a direction perpendicular to flap **116** as described in U.S. patent No. 5,150,971 for additional sealing effectiveness.

Preferably the device **100** is formed by die cutting a single sheet **301** with the flap **116** and the crease **120** are formed during the die-cutting process.

A single sheet **301** suitable to form the device **100** is shown in Fig. 3. Thus Fig. 3 shows the wall structure of the device **100**. The single sheet **301** comprises three layers: a first layer **310** (i.e. the outer layer) that can be paper or cardboard; an optional second layer **320** (i.e. the middle layer) that can be a metallic foil or metallized polymeric material; and a third layer **330** (i.e. the interior or inner layer) that can be a thin layer of polymeric material that is water resistant and flexible, such as polyethylene or polypropylene, laminated thereon to seal the second layer **320** to the first layer **310**. Three layers are preferred because the middle layer **320**, which is sealed to the outer layer **310** by the interior layer **330**, acts as a primary barrier against leakage of the etiological and/or biomedical materials through the outer layer if such material begins to leak from the pouch region. In addition the middle layer **320** prevents light from degrading a specimen in the envelope and prevents leakage of malodorous gas from the envelope. Accordingly, metallic foils (such as aluminum) and metallized polymeric materials are most preferred for the middle layer because such materials prevent such leakage.

Paper or cardboard materials are most preferred for the outer layer **310** in that these can be readily pre-printed with information typically imprinted on mailing envelopes (i.e. postage stamp location, return address information, as well as any pertinent instructions).

Polyethylene and polypropylene are most preferred for the third layer **330** in that these materials are useful in a heat-sealing lamination process because these materials, by their very nature, form a sealed bond upon heating and can be printed thereon.

The first layer **310** is typically about 4 to about 6 mils thick; the middle layer **320** is typically about 0.27 to about 0.33 mils thick; and the third layer **330** is typically about 1 to about 10 mils thick.

A layer of adhesive **130**, as previously detailed, is preferably added onto the third layer **330** and can begin directly above the insertion region **115**, covering the flap **116**, and region **131**. When completed, the mailing device can have mailing information printed on sides **101a** or **101b**, as well as any other pertinent and/or additional information.

At least a portion of the surface **331** of the third layer **330** that faces the first outer layer **310** has printing thereon, such as a biohazard warning. This can be effected by corona treating the surface **331**, and printing with a flood coating **332** of orange or red, and then printing with a plurality of spaced apart black biohazard warnings **333**. The ink used can be a conventional solvent based ink printed using a lithographic or flexographic technique. The printing is performed before laminating the layers together. Because the printing is on the protected surface **331** of the third layer **330**, it is protected from the contents of the envelope **100**. Thus samples such a liquids, i.e. blood, or semi-solids, such as fecal specimens, do not adversely affect the printing. The third layer is substantially light transmissive, and preferably substantially transparent so that the printing **332** and **335** is visible.

The laminate can contain additional layers. For example, with reference to Fig. 4, there is shown a laminate **301'** with an additional polymeric layer **340** between the outer layer **310** and the middle layer **320**. This layer **310** can be about 0.5 mils thick. Also an additional layer or barrier (not shown) can be layered on top of the third layer **330** to form a pocket within the envelope to act as additional security against any potential leakage from an etiologic agent and/or biomedical material inserted into the device, as described in U.S. Patent No. 5,150,971.

Also, the biohazard printing need not be on the surface **331** of the third layer **330** facing the first layer **310**. Rather, as shown in Fig. 5, the printed warning of a laminate **301''** can be on the opposed surface **332** of the laminate, wherein the printing is protected by a protective layer **350** which is substantially light-transmissive, and preferably substantially transparent. In this version fo the invention, this protective layer **350** need not encompass the entire inside of the device **100** but rather only needs to be over the printing. The protective layer can be about 0.5 mils thick. In this version of the invention, it is not necessary that the third layer **330** be light transmissive.

**EXAMPLE**

An envelope device is made from a four layer laminate comprising, from the outside to the inside, paper/polyethylene/aluminum foil/polyethylene. Both polyethylene layers are low density polyethylene, where the printed layer has a thickness of about 1.5 mils and the other layer has a thickness fo about 0.5 mils.. The foil is aluminum foil having a thickness of about .0003 inch. The paper is bleached Kraft paper and has a basis weight of 76 pounds per ream, and a thickness of 5.4 mils. The outer surface **330** of the paper is printed as shown in Fig. 1. The outwardly facing surface **331** of the inner layer **330** of polyethylene is printed as shown in Fig. 3. The printing is effected with a flood coating process using red colored type ink for the background, with the black biohazard being printed with black ink. Preferably substantially the entire surface **331** is printed so that no matter where the envelope **100** is opened, the printed indicia is visible.

To use the device **100**, a specimen collection device including an etiologic agent and/or biomedical material is inserted into the interior portion of shipping device **100** at insertion region **115**. A protective tape (not shown) covering adhesive **130** is removed, and the flap **116** is folded along the crease **120** such that the flap **116** securely seals the insertion region **115**. Mailing of the device is then accomplished in a manner as defined by the rules and requirements for utilization of the applicable postal service. When received by a healthcare professional, the test device can be removed by cutting or tearing open the mailing device along any edge. If the device is inadvertently opened, the printed biohazard warning becomes visible.

All features disclosed in the specification, including the claims, abstracts, and drawings, and all the steps in any method or process disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. Each feature disclosed in the specification, including the claims, abstract, and drawings, can be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

Any element in a claim that does not explicitly state "means" for performing a specified function or "step" for performing a specified function, should not be interpreted as a "means" or "step" clause as specified in 35 U.S.C. § 112.

Although the present invention has been described in considerable detail with reference to the preferred versions thereof, other versions are possible.

For example, the printing can be on a surface of a fourth additional layer that faces the first layer **310**. What is important to the present invention is that the innermost layer be substantially light transmissive or transparent, and that it protect the printing from the contents of the device. If there is such a fourth layer, it is not necessary that the third layer be substantially transparent.

Also, lamination need not be used to the join the layers of sheet **301** together. For example, adhesive can be used.

Therefore the scope of the appended claims should not be limited to the description of the preferred versions contained therein.